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510(k) Summary

Trade Name: **Medoff Sliding Plate System (Sterile)**
Common Name: **Metallic bone fixation device**
Product Classification: **II**
Predicate Devices: **Axial Compression Screw and Hawaiian Supracondylar Plate**

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Description/Indications for Use

The sterile Medoff Sliding Plate System includes lag screws, compression screws, locking set screws, and bone plates consisting of a compression slide and a barreled side plate.

The indications for the sterile Medoff Sliding Plate System vary depending on the configuration of the bone plate. Fracture configurations which lend themselves to the general principle of axial compression should be those that are selected for use with this device. The use of the 4-hole or the 6-hole plating system depends upon surgeon preference and the selection is more related to the size of the surgical exposure and how far down the shaft the fracture extends.

Specific indications for the 135 degree 4-hole standard plate design or 6-hole standard plate design include the following fracture configurations:

- Basicervical fractures of the femur.
- Intertrochanteric fractures of the femur.
- Unstable intertrochanteric fractures of the femur.
- High subtrochanteric fractures of the femur just distal to the level of the lesser trochanter.

Specific indications for the supracondylar plate design include the following fracture configurations:

- Low transverse or short oblique supracondylar fractures of the distal femur.
- T condylar fractures of the femur that can be converted to low transverse or short oblique supracondylar fractures by rigid fixation of condylar fragments with screws.

Material

The sterile Medoff Sliding Plate System is manufactured from stainless steel.

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